

**REMARKS**

**Status of the Claims.**

Claims 1, 2, 4, 6-11, 15, 16, 17, 19, 21, 22, 23-34, and 40 are pending with entry of this amendment, claims 3, 5, 12-14, 18, 20, 35, 36, 38, 39 being cancelled and no claims being added herein. Claims 1 and 22 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (e.g., in the claims as originally filed, in Figures 1 and 2, at page 18, lines 19-20, and the like).

**35 U.S.C. §103(a).**

**A) Claims 1, 2, 4, 6-11, 15, 16, 19, and 21, and claims 22-26, 28-31, 33-37, and 40.**

Claims 1, 2, 4, 6-11, 15, 16, 19, and 21 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Dietrich *et al.* (U.S. Patent 4,612,938) in combination with Chen *et al.* (U.S. Patent 5,445,608) and Lee (U.S. Patent 5,125,904). Claims 22-26, 28-31, 33-37, and 40 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Dietrich *et al.* (U.S. Patent 4,612,938) in combination with Chen *et al.* (U.S. Patent 5,445,608) and Lee (U.S. Patent 5,125,904). In particular, the Examiner asserted that Dietrich *et al.* teaches a device as claimed except for the transparent plug; the self sealing membrane,; and the laser which allows the patient to move about freely. Chen *et al.* was cited as allegedly teaching an indwelling PDT device including multiple lumens, a plug and a valve, and irradiation cover over a long period of time. Lee was cited as allegedly teaching the desirability of employing self sealing membranes and allegedly shows a funnel-shaped opening. Applicants respectfully traverse.

The Examiner is reminded that an obviousness rejection requires a teaching or suggestion to modify the references in the manner indicated by the Examiner. As stated by the Court of Appeals for the Federal Circuit:

Our case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. **“Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight.” Id.**

[emphasis added] *Ecolochem, Inc. v Southern-California Edison Company*,  
— USPQ2d — (Fed. Cir. 2000)

\* \* \*

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. [emphasis added] *In re Fritch*, 23 USPQ 2d 1780, 1783-1784 (Fed. Cir. 1992)

\* \* \*

Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.).

Moreover, it is also well-settled law that:

[I]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP §2143.01, *citing In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984).

In the instant case, claim 1, as amended recites

1. An apparatus for full invasive implantation in a body cavity having an inner surface for use with an external source of light to allow repeated, nontraumatic photodynamic treatments of a patient comprising:

an implantable, inflatable balloon for disposition into said body cavity and which, when inflated, expands into said body cavity to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be disposed in a direct line of sight to at least one point within an interior of said balloon;

an implantable catheter coupled to said inflatable balloon for fully subcutaneous implantation into said patient to access said body cavity;

an optical fiber coupled to the external source of light; and

means for allowing repetitive nontraumatic access of the optical fiber to said body cavity over an extended period of time, through a first lumen of the implantable catheter into said inflatable balloon while segregating the optical fiber from said interior of said balloon and illuminating said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and wherein said first lumen is sealed at both ends, and

wherein said means is disposed such that when said catheter is implanted said means is disposed immediately beneath the skin.

Similarly, claim 22, as amended herein recites:

22. A method of photodynamically, repetitively, nontraumatically treating a tumor resection characterized by a body cavity having an inner surface in a patient using an external light source, said method comprising:

selectively disposing and retaining a photosensitizing drug in cancerous tissue within said inner surface of said body cavity and adjacent thereto;

fully subcutaneously invasively implanting a catheter so that both of a distal end and a proximal end are under the skin of the patient and said proximal end comprises a means for allowing repetitive nontraumatic access of an optical fiber to a second lumen of said catheter over an extended period of time, whereby said implanting places said catheter such that said means is immediately below the skin;

fully subcutaneously invasively implanting an inflatable balloon coupled to said distal end of said catheter into said body cavity thereby providing a catheter comprising a lumen sealed at both ends;

inflating said inflatable balloon in said body cavity by means of a first lumen defined in said catheter to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed by a direct line of sight to at least one point within said balloon;

repetitively disposing an optical fiber through at most the skin of the patient and through said second lumen defined in said catheter to position a distal end of said optical fiber within said inflatable balloon; and

delivering a fractionated dosage of light from the external light source through said optical fiber to effectively photodynamically treat said tumor resection when said distal end of said optical fiber is disposed through the fully subcutaneously implanted catheter so that repetitive but nontraumatic photodynamic treatment is provided.

In other words, the claims are directed to a device, and methods of use thereof, where the device comprises an implantable catheter coupled to an inflatable balloon where the catheter:

- 1) Is fully subcutaneous (i.e., no part protrudes through the skin) when implanted;
- 2) Comprises a lumen sealed at both ends;

- 3) That provides a means for allowing repetitive nontraumatic access of the optical fiber to the body cavity; and
- 4) That is configured such that when implanted the means is disposed immediately beneath the skin.

The cited art simply fails to teach or suggest such a device. Contrary to the Examiner's assertion, Dietrich *et al.* does not teach a device as claimed, since the device disclosed by Dietrich cannot function as a fully subcutaneous device, does not comprise a lumen sealed at both ends, and does not provide a means for repetitive nontraumatic access of an optical fiber. To the contrary, Dietrich *et al.* disclose a device described as follows:

FIG. 1 shows a bladder as the organ cavity 1 on whose interior walls 2 there are tumor 3. In this embodiment, the interior of organ cavity 1 is filled completely with a liquid light dispersing or scattering medium 4 which may be inserted through a catheter 5 having a continuous outflow 8' and inflow 8 for the dispersing or scattering medium 4.

\* \* \*

FIG. 2 shows a further possibility for diagnosis/therapy. In this case, the organ cavity 1 is filled only partially with a liquid, light dispersing or scattering medium 4 which is contained in a transparent balloon 17 at the end of a catheter 18 with or without a wire cage. In this embodiment, two light conductors 19 and 20 are introduced separately via the catheter 18 into the dispersing medium 4 within the balloon 17 but only one of the light conductors, i.e. the light conductor 19 is used for irradiation for diagnosis and therapy. Either light from laser 21 (therapy) or from laser 22 (diagnosis) is used for this purpose. The second light conductor 20 serves exclusively to couple out the measuring signal 23 for diagnostic purposes which is conducted to detector 25 via a suitable filter 24. Evaluation and control of therapy/diagnosis are effected corresponding to the embodiment of FIG. 1.

In both embodiments, an open catheter is necessary for introduction of the dispersing or scattering medium. In addition, the catheter is open to permit insertion of the light conductor(s). Dietrich *et al.* thus fails to disclose the presently claimed invention.

Modification of the devices disclosed by Dietrich *et al.* in accordance with the teachings of Chen *et al.* fails to remedy this defect.

Of the cited references, only Chen *et al.* arguably teaches a fully subcutaneous device. Chen *et al.* identified three embodiments of their invention illustrated by Figures 2A, 2B, and 2C. Of these, only Figures 2A and 2B illustrate embodiments, that are, arguably fully subcutaneous. It is noted, however, that in these embodiments, the proximal end of the device (head 46) comprises an LED or LED drive module 56 and an optional photoreactive agent reservoir 52:

**Three different configurations for the implantable probe system are disclosed in FIGS. 2A through 2C.** In these and subsequent figures, elements of the invention that have a common function, but a different shape or configuration are identified by the same numeric reference numeral, distinguished from each other by the addition of a ' or " notation. For example, in FIG. 2A, an implantable probe 40 is illustrated as used for treating a malignant brain tumor 42, while in FIG. 2B, an implantable probe 40' is shown, and FIG. 2C shows an implantable probe 40". In each of these three different configurations of the implantable probe system, an array 54 of LEDs are disposed within the implantable probe and these LEDs are provided with electrical power through leads (not shown), which extend through a flexible catheter 44 (or through a flexible catheter 44' in the embodiment of FIG. 2C). In this and most other embodiments of the implantable probes, it is contemplated that solid-state laser diode (LDs) chips could be used instead of the LEDs as the source of the light. Implantable probe 40 in the first of these three figures includes a head 46 that is disposed on a proximal end of flexible catheter 44, for example, between a patient's scalp 48 and skull 50. **Inside head 46 of the device are disposed an LED (or LD) drive module 56 and an optional photoreactive agent reservoir 52 that holds a photoreactive agent** that is periodically perfused through flexible catheter 44 into malignant brain tumor 42 during the extended exposure of the treatment site to light from the LEDs. [emphasis added] (col. 9, lines 18-47).

The LED or LED drive module is not described as optional in these embodiments. Moreover, one of skill in the art reading Chen *et al.* would recognize the LED or LED drive module as essential to the subcutaneous embodiments, since Chen *et al.* fails to teach or suggest any other means of introducing light into a subcutaneous device. Indeed, one may view Chen *et al.* as teaching away from such means by advocating incorporation of the LED or LED drive module within the implanted device.

Utilizing the teaching of Chen *et al.* to modify the device of Dietrich *et al.* to produce a fully subcutaneous device would thus lead one of skill in the art to a device wherein the LED or LED drive module is within the implanted device. In addition, such a modification would lead one of skill

away from a device comprising a means for allowing repetitive nontraumatic access of the optical fiber to said body cavity as in the presently claimed invention. Such a means would suggest and even dictate elimination of the LED or LED drive module illustrated by Chen *et al.* The presence of the LED or LED drive module would physically block entrance of the optical fiber (from outside the body) into the lumen of the Chen *et al.* device. Moreover, Chen *et al.* expressly teaches that where an external light or power source is to be used, then the device will not be fully subcutaneous:

FIG. 2C is a third embodiment of the light source that is coupled to an external power source through a flexible catheter; [col. 5, lines 63-65].

In addition, to produce a device where when the catheter is implanted the means for nontraumatic access "disposed immediately beneath the skin" would require elimination of the head 46. However, the only embodiment taught or suggested by Chen *et al.* lacking a head 46 is a device that is not fully subcutaneous (see, e.g., Figure 2C).

Modification of the teachings of Dietrich *et al.* and/or Chen *et al.* by the teachings of Lee still fails to teach or suggest the present invention. Lee *et al.* disclose a device that cannot be fully subcutaneous. Lee discloses a splittable hemostatic valve and introducer sheath for introducing leads or catheters into an artery (see, e.g., abstract). The device is thus an "external" device that is manipulated, e.g., by a surgeon, to introduce a catheter or electrode into an artery.

The device is clearly not intended and unsuited for fully subcutaneous implantation. For example, distal to the valve membrane 22 is a side arm to provide fluid drip which would be unsuitable for an implanted device:

The invention is a sheath assembly for use with a lead or catheter comprising an introducer sheath, and a hemostatic valve coupled to the introducer sheath. The hemostatic valve and introducer sheath are arranged and configured to permit introduction of at least one lead or catheter therethrough. An element is provided to permit removal of the hemostatic valve and introducer sheath from the catheter disposed therethrough without requiring the introducer sheath and hemostatic valve to be removed from an end of the catheter. A side arm is connected to hemostatic valve cage and provides continuous fluid drip in order to prevent clot formation in the sheath lumen. [emphasis added] (col. 2, lines 52-64)

In addition, the central feature of the Lee invention is the splittable sheath that permits removal of the hemostatic valve and introducer sheath (*see supra*). In addition, the specification teaches that in use:

It is contemplated that at the end of the operation the physician will grasp opposing flange portions 38 and 40 to peel them apart while pulling out the sheath and holding the lead. This will cause valve body 16 to tear along a section line depicted by dotted lines 42 through the body of valve assembly 14. Both body portions 16a and b may be scored to facilitate this tearing. In addition the bonding of the body portions 16a and 16b assists in tearing the inner body portion as the outer body portion is being torn along its corresponding tear line. The portions become through the bonding as a single body and the fracture or tear propagates from the outer body portion through the inner body portion. Membrane 22 has a weak line or score line and can easily be removed from the lead. [emphasis added] (col. 6, lines 10-24)

Lee thus expressly teaches a membrane 22 having a weak line or score line that is removed (*i.e.*, torn away) from the lead and not left in the surgical site. Lee thus expressly teaches away from a device comprising a subcutaneously implanted membrane. It is also noted that the device disclosed by Lee has an open distal end. The combination of Dietrich *et al.*, Chen *et al.*, and Lee *et al.* thus simply fails to lead one of skill to a device designed to be fully subcutaneous (*i.e.*, no part protrudes through the skin), that comprises a lumen sealed at both ends, and that provides a means for allowing repetitive nontraumatic access of the optical fiber to the body cavity.

The Examiner is further reminded that when considering the prior art:

All of the facts must be considered and it is not realistic \* \* \* within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. [emphasis added] *In re Lunsford* 148 USPQ 721, 725 (CCPA 1966) citing *In re Wesslau*, 147 USPQ 391, 393 (CCPA, 1965)

In the instant case, only Cnen *et al.* arguably teaches a fully subcutaneous device, but in that context teaches that the subcutaneous devices contain an LED or LED drive module. Lee

arguably teaches a self-healing membrane, but that membrane is weakened with a "weak line or score line" is in a device that is not fully subcutaneous and that contains a sheath that is splittable. Dietrich *et al.* teaches a device that is neither subcutaneous nor comprises a lumen sealed at both ends.

Why would one of skill in the art select an subcutaneous configuration from Chen *et al.* while ignoring the teaching that fully subcutaneous devices contain an internal LED or LED drive module, select from Lee a diaphragm eliminating weakness or score line (contrary to Lee's teaching), while ignoring the splittable sheath or select a device as taught by Dietrich which is not fully subcutaneous? The Examiner has offered no particular findings as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected the particular recited components to the exclusion of the other teachings profvided in the references.

Accordingly, the Examiner has failed to make his *prima facie* case under 35 U.S.C. §103(a) and the rejection of claims 1, 2, 4, 6-11, 15, 16, 19, and 21 on these grounds should be withdrawn.

**B) Claims 17 and 32.**

Claims 17 and 32 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Dietrich *et al.* in combination with Chen *et al.*, and Lee as discussed above, further in view of Hayman *et al.* (U.S. Patent 5,267,960). In particular the Examiner cited Hayman *et al.* as allegedly teaching the desirability of combining PDT and radiation treatment.

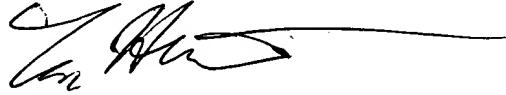
As explained above, Dietrich *et al.*, Chen *et al.*, and Lee fail to teach or suggest a device designed to be fully subcutaneous (i.e., no part protrudes through the skin), that comprises a lumen sealed at both ends, and that provides a means for allowing repetitive nontraumatic access of the optical fiber to the body cavity. The defects in these references, described above, are not remedied by Hayman *et al.* Hayman *et al.* simply describes a device for installing a catheter in a patient's body for use in delivery of a radioactive source to an from the site of a tumor (*see, e.g.*, abstract). The device described therein is clearly not designed to be implanted in a fully subcutaneous manner. In addition, the device does not have a lumen sealed at both ends. The combination of all of the cited references thus fails to teach or suggest the invention of claim 17 and the rejection of this claim under 35 U.S.C. §103(a) should be withdrawn.,

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner wishes to maintain any of the rejections, Applicants respectfully request a telephone conference to discuss this matter. In addition, if a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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